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| 10/762,204 | 01/20/2004 | Kevin A. Thomas | MA9665P | 2530 |

7590 07/09/2007
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EXAMINER

HAGOPIAN, CASEY SHEA

| | |
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| ART UNIT | PAPER NUMBER |
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1615

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| MAIL DATE | DELIVERY MODE |
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07/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/762,204 | Applicant(s) THOMAS ET AL. | |
| | Examiner Casey Hagopian | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 5/1/2007. It is noted that in the Interviews between the Examiner and Applicant's representative, discussion of proposed amendments were only discussed to the independent claims. The examiner was unaware of any proposed amendments to the depending claims. Also, the Examiner requested Applicant's representative to point out where in Applicant's disclosure support could be found for each of the amendments. Applicant's Amendment/Remarks submitted 5/1/2007 does not fulfill said request.

Claims 1-48 are currently pending. Claims 1, 4, 5, 9, 12, 30, 35 and 45-47 have been amended.

MAINTAINED REJECTIONS

The following rejections have been maintained from the previous Office Action dated 3/15/2007:

Art-Based Rejections

It is noted that the instant claims are product claims. There are many instances of product-by-process recitations, for example, "thermally formed" in claims 1 and 30, "the implant body is manufactured in the pre-implant configuration" in claims 5 and 47, "are sized to reduce visual obstruction of tissues surrounding the implant when the implant is placed in a patient" in claims 14 and 36 and "formed using an injection molding process" in claims 21 and 22. Determination of patentability is based on the

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product itself, not by the method in which it is made. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113).

It is further be noted that the instant claims contain intended use recitations such as "to permit visualization of a location of the implant without obscuring visualization of changes surrounding the implant when the implant is placed in a patient, and which does not interfere with other imaging modalities such as CT and MRI scans" in claim 1, "to allow for formation of the marker" in claim 3, and "to facilitate radiographic visualization of the implant when the implant is placed in the patient" in claim 30. Said limitations do not alone show patentable distinction. A recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 30-32, 34-39 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Preissman (USPN 6,231,615 B1).

Preissman discloses an enhanced visibility composition for implantation that can be readily observed under fluoroscopy or other imaging techniques such as X-ray, Ct, and MRI (abstract; col. 4, line 21). Said composition comprises a tissue implant material and radiopaque particles having a particle size between about 120 microns and 2200 microns (col. 2, lines 30-35). The tissue implant material is preferably, polymethyl methacrylate (e.g. nonresorbable), however alternative (resorbable) materials disclosed include hydroxyapatite, calcium phosphates, calcium sulfates, polymer based implants including polyglycolic acid and/or polylactic acid compounds and combinations thereof (col. 2, lines 45-59 and col. 6, lines 9-23; claim 7). Also, barium sulfate is disclosed as a radiopaque particle material (col. 2, lines 60). The composition is further disclosed as being injectable (col. 3, lines 34-37) and the composition may further contain additives (col. 4, lines 6-14). In addition, the drawings illustrate the composition's shape and form as well as the relationship between the implant material and particles. Preissman also teaches the limitation, "thermally formed", because the composition advanced by Preissman undergoes polymerization (col. 5, line 26). Polymers such as PMMA are known as exothermic polymers as evidenced by Cuffe et al. (USPN 4,102,567, see col. 2, lines 52-53). Broadly interpreting said limitation, the process of polymerization reads on "thermally formed". Thus, the disclosures of Preissman render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-7, 9-29, 33, 40-44 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over. Preissman in view of Okada et al. (USPN 6,235,225 B1).

Preissman teaches the elements discussed above.

Preissman is silent to the radiopaque marker comprising a polymer additive.

Okada teaches biocompatible implant materials comprising a binder and a raw material mixture of hydroxylapatite and calcium phosphate (abstract). In Example 2, Okada teaches a binding step that incorporates the particular binder, low-density polyethylene. Medium density polyethylene is also considered as a binder (col. 3, lines 64-67). One of ordinary skill in the art would have been motivated to include a binder such as low-density polyethylene or medium density polyethylene because Okada teaches that the binding step produces "very high strength" (col. 3, lines 23-25). A practitioner would reasonably expect an implant material having higher strength that would allow for easier handling and shaping (col. 3, lines 25-30). Thus, in Preissman, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include "a polymeric additive" or "binder" such as low-density polyethylene or medium density polyethylene as suggested by Okada.

Preissman is silent to the particular shape of the implantable composition such as a sheet or a screw. One of ordinary skill in the art would have been motivated to change the shape of the implantable composition advanced by Preissman depending on the particular purpose of the implantable composition. Furthermore, the MPEP teaches that a change in shape is obvious absent persuasive evidence (see also MPEP

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2144.04 (IV)(B)). A practitioner would reasonably expect an implantable composition in a variety of shapes depending on the particular intended use. Thus, in Preissman, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a particular shape such as a sheet or a screw shaped implantable composition.

Preissman and Okada are silent to the particular barium sulfate and polymer additive component percentages. It would also have been obvious to one of ordinary skill in the art to combine already known ingredients in particular weight percentages in order to optimize a composition. A practitioner would reasonably expect an optimized composition by way of routine experimentation. Thus, in Preissman and Okada, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular percentages claimed.

Response to Amendment/Remarks

After careful consideration and examination of the claims and the specification, Applicant's amendments do not appear to overcome all of the rejections of record. Below is a review of each of the previous rejections from the Office Action dated 3/15/2007, a statement of whether the rejection has been withdrawn or maintained, and reasons as to why the rejection has been withdrawn or maintained.

The amendment to the specification renders the rejection of claims 20, 21 and 41 under 35 USC 112, 1st paragraph moot. The amendment does not introduce new

matter because the originally filed claims contained the subject matter added.

Therefore, the rejection of claims 20, 21 and 41 under 35 USC 112, 1st paragraph has been withdrawn.

The amendment to claim 4 remedies the lack of antecedent basis issue previously presented, however the amendment also introduces a new 112, 2nd paragraph issue. See *New Rejections* for details. **Thus, claim 4 stands rejected under 35 USC 112, 2nd paragraph.**

The amendment to claims 1 and 30 do not overcome the rejections under 35 USC 102 and 103. Applicant appears to be attempting to make a distinction between the composition of the prior art and the claimed composition by pointing out when polymerization and formation of the implant shape takes place. However, these limitations do not distinguish the implant claimed from the prior art because the claims are drawn to a composition and the newly added limitations are drawn to what seems to be process limitations. It should be noted that even if the claims were proper product-by-process claims, applicant would still have the burden to show that the claimed invention is different from that of the prior art (i.e., an unexpected result). The prior art teaches the composition claimed including the particular ingredients, **thus the claims stand rejected under 35 USC 102 and 103.**

NEW REJECTIONS

The following rejections are newly added in light of Applicant's amendments submitted 5/1/2007:

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** There is no teaching of "a non-liquid pre-implant configuration, which is defined as a configuration of the implant immediately before implantation" (see independent claims 1 and 30); the subject matter is not properly described as filed. It is noted that contrary to the claims, the specification contains liquid components including canola oil (see pages 6-7). Applicant is invited to identify the portion of the specification that teaches said limitation, as the examiner has not been able to locate the applicable disclosure. The claims within this rejection are examined as written by the applicant; at this time new matter must be considered as part of the claimed subject matter.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites the limitation "further comprises barium sulfate and polymer additive components" in line 2 of the claim. It is unclear as to whether the "polymer additive components" are the same or different from the "polymer additive component" recited in claim 3. Claim 4 depends from claim 3, thus the Examiner is unable to determine if the polymer additive components in claims 3 and 4 are intended to be one in the same or separate entities. If applicant intends the "polymer additive components" to be one in the same then it is suggested that applicant amends claim 4 to remove the limitation, "and polymer additive components" because it is redundant and not further limiting. Correction is respectfully requested.

Pertinent Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Okada et al. (USPN 6,235,225 B1) teaches a shaping step of a hardened material prior to implantation.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

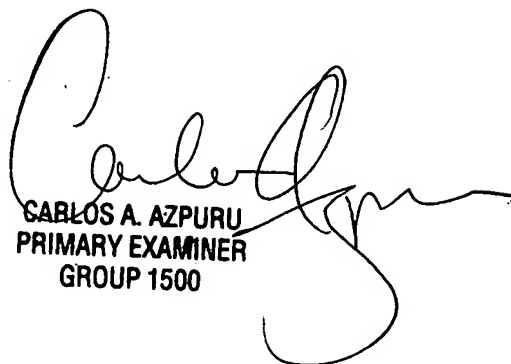
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian
Examiner
Art Unit 1615


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PRIMARY EXAMINER
GROUP 1500